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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/766,608 Filing Date: January 27, 2004 Appellant(s): RIOUX ET AL.

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Group 3700

Michael J. Bolan For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/2/2007 appealing from the Office action mailed 10/13/2006.

Art Unit: 3736

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1, 2, 4, 7-9, 11, 15, 16, 19, 20 and 68-80.

Claims 3, 5, 6, 10, 17 and 18 have been withdrawn from consideration as not directed to the elected Species.

Claims 12-14 and 21-67 have been canceled rather than withdrawn from consideration as indicated in the Office action of 10/13/2006 and the brief.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the rejection of claims 1, 7-9, 11, 15,

Art Unit: 3736

19, 20, 68-71 and 76-80 as being anticipated by US 6,840,909 ("Gatto") is under 35 U.S.C. § 102(e) rather than 35 U.S.C. § 102(b).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| 6,840,909 | GATTO | 1-2005 |
|-----------|---------------|---------|
| 5,949,929 | HAMM | 9-1999 |
| 6,497,706 | BURBANK ET AL | 12-2002 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 7-9, 11, 15, 19, 20, 68-71 and 76-80 are rejected under 35

U.S.C. 102(e) as being anticipated by Gatto (US Patent No. 6,840,909).

In regards to claims 1, 15 and 71, Gatto discloses a system for treating breast tissue, comprising:

a cannula (40 in figure 6) having at least one fluid conveying lumen (43), the cannula configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct (Abstract);

a tissue diagnostic device (12) slidably disposable within the at least one lumen (47); and

Art Unit: 3736

a tissue treatment device (50) slidably disposable within the at least one lumen (49).

Because lumen (47) and lumen (49) are located within lumen (43), the tissue diagnostic device and the tissue treatment device are both disposable within a lumen that conveys fluid.

In regards to claims 7, 19 and 76, Gatto discloses a system, further comprising a media delivery device (200) coupled to the at least one lumen. In regards to claims 8, 20 and 77, Gatto discloses a system, further comprising an aspirator (90) coupled to the at least one lumen. In regards to claims 9, 15 and 78, Gatto discloses a system, further comprising a tissue imaging device (12) slidably disposable within the at least one lumen. In regards to claims 11 and 80, Gatto discloses a system, wherein the imaging device comprises an endoscope (12). In regards to claim 68, Gatto discloses a system, wherein the tissue diagnostic device (12) and the tissue treatment device (49) are slidably disposable within the same one of the at least one lumen (43). In regards to claim 69, Gatto discloses a system, wherein the at least one lumen (43) comprises two lumens (47 & 49). In regards to claim 70, Gatto discloses a system, wherein the tissue treatment device (50) is slidably disposable within the lumen (49). In regards to claim 79, Gatto discloses a system, wherein the imaging device comprises a CCD camera (Column 8, lines 8-34).

Claims 2, 72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable

Art Unit: 3736

over Gatto in view of Hamm (US Patent No. 5,949,929). In regards to claims 2 & 72, Gatto discloses a system with all of the aforementioned elements. However, Gatto does not disclose a system, wherein the tissue diagnostic device comprises a spectrometer. Hamm, however, discloses a system wherein the tissue diagnostic device comprises a spectrometer (46). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Hamm to incorporate a spectrometer with Gatto in order to analyze the spectroscopic data to determine the probability of a malignancy (Column 3, lines 45-51). Furthermore, in regards to claim 75, Gatto does not disclose an optical fiber for delivering laser energy. However, Hamm discloses an optical fiber for delivering laser energy (101). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Hamm to incorporate an optical fiber with Gatto in order to provide optical feedback to the clinician (Column 1, lines 13-25).

Claims 4, 16, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto in view of Burbank et al (US Patent No. 6,497,706). In regards to claim 4, 16, 73, & 74, Gatto discloses a system with all of the aforementioned elements. However, Gatto does not disclose a system, wherein the tissue treatment device comprises an ablation electrode, which have two electrodes in a bipolar arrangement. Burbank et al., however discloses a system, wherein the tissue treatment device comprises an ablation electrode having two electrodes in a bipolar arrangement (Column 2, lines 11-15 & Figure 2, 12 & 13). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Burbank et al. to incorporate

Art Unit: 3736

ablation electrodes with Gatto in order to provide a means for separating and capturing a tissue specimen from the target tissue site (Column 1, line 65 - Column 2, line 4).

(10) Response to Argument

A. Rejection under 35 U.S.C. 102(e) over Gatto

The appellant argues that the tissue diagnostic device and the tissue treatment device are not slidably disposable within the lumen of the cannula of Gatto. In particular, the appellant disagrees with the argument that lumens (47, 49) are disposed in the lumen (43) because the lumens (47, 49, 52, 54) are separate and distinct from each other. The appellant states, "the only logical way in which a lumen can be disposed within another lumen is if they are in a concentric relationship, that is, one lumen is completely surrounded by the other lumen. Otherwise the respective lumens will be in a side-by-side arrangement, in which case, the lumens cannot be considered to be disposed in one another" (pages 6-7 of the brief).

In response, Gatto expressly defines reference numeral (43) as a cylindrical inner channel defined by outer cannula or sheath (42) (column 6, lines 63-65). A cylindrical inner channel clearly reads on a broadest, reasonably interpretation of a lumen. Two tubes (46, 48) are eccentrically mounted within the lumen (43). Each tube (46, 48) defines a respective lumen (47, 49). As shown in figure 6, the lumens (47, 49) are clearly located within the larger lumen (43). In a sense, the tubes (46, 48) divide the larger lumen into sub-lumens. Even though lumens (47, 49) may be considered in a side-by-side arrangement relative to each each other, both lumens (47, 49) remain disposed within the larger lumen (43). Therefore, devices placed in lumens (47, 49) can

Art Unit: 3736

be considered within the larger lumen (43). The claim language does not preclude reading the cylindrical inner channel (43) expressly defined by Gatto on the lumen recited in the claim language. Gatto is considered sufficient to meet the language of the rejected claims.

The appellant's argument regarding single extrusion does not affect the above line of reasoning.

B. Rejection under 35 U.S.C. 103(a) over Gatto and Hamm

As discussed above, the disclosure of Gatto is considered sufficient to meet the limitations at issue.

C. Rejection under 35 U.S.C. 103(a) over Gatto and Burbank

The appellant further argues that the electrodes (12, 13) of Burbank are used "to cut and capture a tissue specimen from a target tissue site in a biopsy procedure - not to treat the target tissue site." In response, it is respectfully submitted that removing suspect tissue in a biopsy is by itself a form of treatment.

The appellant further argues that incorporating the biopsy electrodes (12, 13), intended for cutting whole tissue samples, from Burbank into the cannula assembly of Gatto would defeat its purpose of taking a cytological sample. In response, one of ordinary skill in the art would have been motivated to use the ablation electrodes as an alternative means to immediately remove or ablate suspect tissue when discovered by the system of Gatto. This modification would not change the overall purpose of Gatto, namely, the removal of tissue and cells from an abnormal area (see abstract of Gatto). The modification is a simple substitution of one means for treatment/resection/biopsy for

Art Unit: 3736

another and it would have been routine for one having ordinary skill in the art to incorporate the ablation electrodes with the probe of Gatto

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael Apanius

Max Hindenk

Robin Evans